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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	Art Unit: 1644
)	
JIANG, et al.)	Examiner:
)	
Serial No.: 10/502,085)	Washington, D.C.
)	
Filed: April 12, 2005)	June 7, 2007
)	
For: IMMUNOSTIMULATORY,)	Docket No.: JIANG=4A
COVALENTLY LIPIDATED)	
OLIGONUCLEOTIDES)	Confirmation No.: 3733

INFORMATION DISCLOSURE STATEMENT [IDS]

U.S. Patent and Trademark Office
Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314

S i r :

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:

☐ A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application. See 37 CFR 1.97(b)(1) and (3).

☒ B. before the mailing date of a first office action on the merits. See 37 CFR 1.97(b).

☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below). See 37 CFR 1.97(c)(2).

☐ i. Counsel certifies that, upon information and

belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

- [] ii. A Credit Card Authorization, authorizing payment for the fee set forth in 1.17(p), presently believed to be \$180, is attached.

[] D. after (A), (B) and (C) above, but before payment of the issue fee. Applicant petitions under 37 C.F.R. 1.97(d) for consideration of this IDS. A Credit Card Authorization, authorizing payment for the fee set forth in 1.17(p)(1), presently believed to be \$180 is attached. Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

[] E. As a submission in accordance with the transitional procedure for limited examination after final rejection pursuant to 37 CFR §1.129(a). Pursuant to MPEP §706.07(g), page 700-66, col. 2 (August 2001), this IDS is treated as if filed with a period set forth in 37 CFR §1.97(b) and considered without the petition and petition fee required by 1.97(d).

[] F. As a submission with or after a request for continued examination under CFR §1.114, and before the mailing of a first office action on the RCE. See 37 CFR §1.97(b)(4).

2. In accordance with 37 C.F.R. 1.98, this IDS includes a

list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document is attached, except as explained below.

[] While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged"). Counsel has used a list provided to him by Applicants, and not transferred the information to a PTO-1449, to avoid the risk of any inadvertent error in transferring the information.

[X] A. Documents AA-AS are U.S. Patents or U.S. Patent Publications, and hence copies of these documents have not been provided. See 37 CFR 1.98(a)(2)(ii).

[] B. Documents _____ are deemed substantially cumulative to documents _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

[] C. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

[insert serial number/filing date]

Applicants identify these documents by attaching hereto copies of the form PTO-892s and PTO-1449s from the files of the prior applications or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application. If copies of any of these documents cannot be found in the files of the prior applications, the Examiner is requested to so notify counsel before taking action in this case, so replacement copies can be submitted. While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for

consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged") and no prohibition on submitting a copy of a form PTO-1449 or form PTO-892 from a prior case. Indeed, the re-use of such forms is desirable as it avoids error in transferring the information, and evidences that the reference was considered in a prior application. A previously accepted PTO-1449, or an examiner-prepared PTO-892, necessarily complies with §1.98(b).

[X] 3. Document AY is not in the English language. In accordance with 1.98(a)(3), Applicants state:

[X] document AY already contains an English language abstract, summary or claim set.

[X] document BC is an English language abstract of a foreign language document not presently in applicants possession or control.

4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

5. If the month of publication of a nonpatent reference is not stated, it is because it is not apparent from review of the reference. If requested to do so by the Examiner, Applicants will attempt to locate and write to the publisher.

If the publication date of a cited document is set forth only as a publication year, and that year is prior to the year of filing or, if priority is claimed, year of priority of this application, then the particular month of publication is not in issue. Likewise if that publication year is after the year of filing of this application, the month of publication is not in issue.

If the date of publication of a nonpatent reference is stated, then, except as explained below, it is the nominal date stated in the reference, or in a larger document (journal or

book) from which the reference was extracted. Applicants reserve the right to challenge this date by contacting the publisher to determine the actual shipment date, or by contacting recipients to determine the receipt dates.

6. Other information being provided for the examiner's consideration follows:

[insert other information]

7. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

8. The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this paper or credit any overpayment to Deposit Account No. 02-4035.

Respectfully submitted,

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SUBSTITUTE FOR FORM IPC/SB/08		ATTY DOCKET NO: JIANG=4A		SERIAL NO: 10/502,085		
INFORMATION DISCLOSURE STATEMENT LIST OF DOCUMENTS CITED BY APPLICANT		FIRST INVENTOR: Zi-Hua Jiang				
		FILING DATE: April 12, 2005				
		CONFIRMATION NO.: 3733		ART UNIT: 1644		
U.S. PATENT DOCUMENTS (include at least patentee, patent/pub number and filing/issue/pub date)						
EXAM. INITIAL	ID	DOCUMENT NUMBER	FILING, ISSUE OR PUBLICATION DATE MM-DD-YYYY	PATENTEE OR APPLICANT	Relevant Passage(s)	T*
	AA	4,235,871	11-25-1980	PAPAHADJOPOULOS et al.		
	AB	4,501,728	02-26-1985	GEHO et al.		
	AC	4,837,028	06-06-1989	ALLEN		
	AD	5,019,369	05-28-1991	PRESANT et al.		
	AE	5,223,263	06-29-1993	HOSTETLER		
	AF	5,416,203	05-16-1995	LETSINGER		
	AG	5,646,126	07-08-1997	CHENG et al.		
	AH	5,677,439	10-14-1997	WEIS et al.		
	AI	5,717,083	02-10-1998	COOK et al.		
	AJ	5,744,144	04-28-1998	FINN et al.		
	AK	5,750,669	05-12-1998	RÖSCH et al.		
	AL	5,756,352	05-26-1998	SRIDHAR et al.		
	AM	5,827,831	10-27-1998	HOSTETLER et al.		
	AN	6,013,779	01-11-2000	WONG et al.		
	AO	6,086,898	07-11-2000	DEKRUYFF et al.		
	AP	6,111,085	08-29-2000	COOK et al.		
	AQ	6,114,513	09-05-2000	COOK et al.		
	AR	6,300,319	10-09-2001	MANOHARAN		
	AS	6,344,203	02-05-2002	SANDRIN et al.		
FOREIGN PATENT DOCUMENTS (include at least document number, publication date and country)						
EXAM. INITIAL	ID	COUNTRY CODE & DOCUMENT NUMBER	PUBLICATION DATE MM-DD-YYYY	PATENTEE OR APPLICANT	Relevant Passage(s)	T*
	AT	WO 98/18810	05-07-1998	THE UNIVERSITY OF IOWA RESEARCH FOUNDATION		E
EXAMINER				DATE CONSIDERED		
EXAMINER: Initial if reference considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.						

* "Relevant Passages" column is optional. Put check in "T" column if English translation of entire document included. If English language abstract included, put A in this box. If ref. in English, put "E". If requirement otherwise met, put O.

SUBSTITUTE FOR FORM IPC/SB/08 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT LIST OF DOCUMENTS CITED BY APPLICANT			ATTY DOCKET NO: JIANG =4A		SERIAL NO: 10/502,085	
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EXAM. INITIAL	ID	COUNTRY CODE & DOCUMENT NUMBER	PUBLICATION DATE MM-DD-YYYY	PATENTEE OR APPLICANT	Relevant Passage(s)	T*
	AU	WO 98/40100	09-17-1998	OTTAWA CIVIC LOEB RESEARCH INSTITUTE		E
	AV	WO 99/51259	10-14-1999	UNIVERSITY OF IOWA RESEARCH FOUNDATION		E
	AW	WO 99/61056	12-02-1999	LOEB HEALTH RESEARCH INSTITUTE AT THE OTTAWA HOSPITAL		E
	AX	WO 00/54803	09-21-2000	PANACEA PHARMACEUTICALS, LLC		E
	AY	WO 01/07055	02-02-2001	MOLOGEN FORSCHUNGS-, ENTWICK-LUNGS-UND VERTRIEBS GMBH		A
	AZ	WO 01/12804	02-22-2001	HYBRIDON, INC.		E
	BA	WO 01/83503	11-08-2001	HYBRIDON, INC.		E
	BB	WO 01/97843	12-27-2001	UNIVERSITY OF IOWA RESEARCH FOUNDATION		E
	BC	JP 10 251292	12-31-1998	MATSUDA AKIRA		A
OTHER DOCUMENTS (include author, title, name of publication, volume, pages and date of publication) Please list in alphabetical order.						
	BD	ALEXOPOULOU, et al., "Recognition of double-stranded RNA and activation of NF-kB by Toll-like receptor 3", <u>NATURE</u> , vol. 413, pp. 732-738, October 18, 2001.				
	BE	DAVIS, et al., "Drug Leads from Combinatorial Phosphodiester Libraries", <u>MED. CHEM.</u> , VOL. 38, PP. 4363-4366, 1995.				
	BF	HEMMI, et al., "A Toll-like receptor recognizes bacterial DNA", <u>NATURE</u> , vol. 408, pp. 740-745, December 7, 2000.				
	BG	HILTBOLD, et al., "Naturally Processed Class II Epitope from the Tumor Antigen MUC1 Primes Human CD4 ⁺ T Cells", <u>CANCER RESEARCH</u> , vol. 58, pp. 5066-5070, November 15, 1998.				
EXAMINER			DATE CONSIDERED			
EXAMINER: Initial if reference considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.						

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BH	KABANOV, et al., "A new class of antivirals: antisense oligonucleotides combined with a hydrophobic substituent effectively inhibit influenza virus reproduction and synthesis of virus-specific proteins in MDCK cells", <u>FEBS LETTERS</u> , vol. 259, no. 2, pp. 327-330, January 1990.		
BI	KRIEG, et al., "CpG motifs in bacterial DNA trigger direct B-cell activation", <u>NATURE</u> , vol. 374, pp. 546-549, April 6, 1995.		
BJ	MATYSIAK, et al., "Acetall Oligonucleotide Conjugates In Antisense Strategy", <u>NUCLEOSIDES & NUCLEOTIDES</u> , vol. 16, pp. 855-861, 1997.		
BK	MENSITORFF-POUILLY, et al., "Human MUC1 mucin: a multifaceted glycoprotein", <u>THE INTERNATIONAL JOURNAL OF BIOLOGICAL MARKERS</u> , vol. 15, no. 4, pp. 343-356, 2000.		
BL	MENSITORFF-POUILLY, et al., "Reactivity of Natural and Induced Human Antibodies To MUC1 Mucin with MUC1 Peptides and N-Acetylgalactosamine (GalNAc) Peptides", <u>INT. J. CANCER</u> , vol. 86, pp. 702-712, 2000.		
BM	MENSITORFF-POUILLY, et al., "Survival in Early Breast Cancer Patients is Favorably Influenced by a Natural Humoral Immune Response to Polymorphic Epithelial Mucin", <u>JOURNAL OF CLINICAL ONCOLOGY</u> , vol. 18, no. 3, pp. 574-583, February 2000.		
BN	MEYLAN, et al., "Atom/Fragment Contribution Method for Estimating Octanol-Water Partition Coefficients", <u>JOURNAL OF PHARMACEUTICAL SCIENCES</u> , vol. 84, no. 1, pp. 83-92, January 1995.		
BO	MÖLLER, et al., "NMR-based determination of the binding epitope and conformational analysis of MUC-1 glycopeptides and peptides bound to the breast cancer-selective monoclonal antibody SM3", <u>EUR. J. BIOCHEM.</u> , vol. 269, pp. 1444-1455, 2002.		
BP	RAGUPATHI, et al., "Vaccines prepared with sialyl-Tn and sialyl-Tn trimers using the 4-(4-maleimidomethyl) cyclohexane-1-carboxyl hydrazide linker group result in optimal antibody titers against ovine submaxillary mucin and sialyl-Tn-positive tumor cells", <u>CANCER IMMUNOL. IMMUNOTHER.</u> , vol. 48, pp. 1-8, 1999.		
BQ	REDDISH, et al., "Specificities of anti-sialyl-Tn and anti-Tn monoclonal antibodies generated using novel clustered synthetic glycopeptide epitopes", <u>GLYCOCONJUGATE JOURNAL</u> , vol. 14, pp. 549-560, 1997.		
BR	SCHNEIDER, et al., "Oligonucleotides Containing Flexible Nucleoside Analogues", <u>J. AM. CHEM. SOC.</u> , VOL. 112, PP. 453-455, 1990.		
BS	SCHREIBER, et al., "Binding of Tumor Antigen Mucin (MUC1) Derived Peptides to the Heat Shock Protein DnaK", <u>ANTICANCER RESEARCH</u> , vol. 20, pp. 3093-3098, 2000.		
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OTHER DOCUMENTS (include author, title, name of publication, volume, pages and date of publication)			
	BT	SHEA, et al. "Synthesis, hybridization properties and antiviral activity of lipid-oligodeoxynucleotide conjugates", <u>NUCLEIC ACIDS RESEARCH</u> , vol. 18, no. 13, pp. 3777-3783, 1990.	
	BU	SOARES, et al., "Three Different Vaccines Based on the 140-Amino Acid MUC1 Peptide with Seven Tandemly Repeated Tumor-Specific Epitopes Elicit Distinct Immune Effector Mechanisms in Wild-Type Versus MUC1-Transgenic Mice with Different Potential for Tumor Rejection", <u>THE JOURNAL OF IMMUNOLOGY</u> , vol. 166, pp. 6555-6563, 2001.	
	BV	SONEHARA, et al., "Hexamer Palindromic Oligonucleotides with 5'-CG-3' Motif(s) Induce Production of Interferon", <u>JOURNAL OF INTERFERON AND CYTOKINE RESEARCH</u> , vol. 16, pp. 799-803, 1996.	
	BW	TAKEUCHI, et al., "Differential Roles of TLR2 and TLR4 in Recognition of Gram-Negative and Gram-Positive Bacterial Cell Wall Components", <u>IMMUNITY</u> , vol. 11, pp. 443-451, October 1999.	
	BX	UHLMANN, et al., "Antisense Oligonucleotides: A New Therapeutic Principle", <u>CHEMICAL REVIEWS</u> , vol. 90, no. 4, pp. 544-584, June 1990.	
	BY	UHLMANN, et al., "PNA: Synthetic Polyamide Nucleic Acids with Unusual Binding Properties", <u>ANGEW. CHEM. INT. ED.</u> , vol. 37, pp. 2797-2823, 1998.	
	BZ	USMAN, et al., "Preparation of Glyceronucleoside Phosphoramidite Synthons and Their Use In The solid Phase Synthesis of Acyclic Oligonucleotides", <u>TETRAHEDRON LETTERS</u> , vol. 29, no. 38, pp. 4831-4834, 1988.	
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